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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/518,870

08/29/2005

Masayoshi Shichiri

4439-4028

5652

85775 7590 04/17/2009

Locke Lord Bissell & Liddell LLP

Attn: IP Docketing

Three World Financial Center

New York, NY 10281-2101

EXAMINER

PAGONAKIS, ANNA

ART UNIT

PAPER NUMBER

1614

NOTIFICATION DATE

DELIVERY MODE

04/17/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ptopatentcommunication@lockelord.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/518,870	<b>Applicant(s)</b> SHICHIRI ET AL.	
	<b>Examiner</b> ANNA PAGONAKIS	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-11 and 15-23 is/are pending in the application.
- 4a) Of the above claim(s) 5-11 and 15-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

**Claims 1-3 are currently under examination and the subject of this Office Action.**

Applicant's amendment filed 1/21/2009 has been received and entered into the present application.

Claims 1-3, 5-11, 15-23 are currently pending. Accordingly, claims 1-2 have been amended and claims 5-11 and 15-23 remain withdrawn.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Present claim 1, and the claims dependent therefrom, reads upon a pharmaceutical composition comprising a therapeutically effective amount of rifampicin and the inhibiting of a malignant tumor.

Instant claims 1-3, are directed to non-statutory subject matter because the claims are clearly intended to encompass a product and a process. Specifically, claim 1 recites limitations clearly directed to a product, i.e. an angiogenesis inhibitor comprising rifampicin but then goes on to state limitations that are clearly directed to a process, i.e. the inhibiting of a malignant tumor. Accordingly, it seems that Applicant intends to claim a product and process. The overlap between the two statutory categories of invention (i.e., product and process) renders the subject matter of instant claims 1-3 non-statutory under 35 U.S.C. 101 because 35 U.S.C. 101 is drafted in a manner so as to set forth the statutory classes of

Art Unit: 1614

invention *in the alternative only*. Please see *Ex parte Lyell*, 17 USPQ2d 1548 (Bd. Pat. App. & Inter. 1990) Id. at 1551.

To overcome the instant rejection, it is suggested to Applicant to reword the claims to recite the inhibiting properties as a characteristic or a capability of the claimed product. Note that this is a suggestion to overcome the present rejection under 35 U.S.C. 101 and that the adoption of such a suggestion does not necessarily equate to the obviation of any other rejections set forth in the instant Office Action.

This rejection is necessitated by Applicant's amendment to the claims because the present amendment to independent claim 1 now presents the inhibiting of a malignant tumor as an active step of the claimed product, whereas the previously pending claims recited this limitation as a property or characteristic of the claimed product. This newly amended active step of inhibiting is tantamount to a process limitations rather than simply a property or capability of the claimed composition and, thus, renders the instantly amended claims non-statutory pursuant to the provisions of 35 U.S.C. 101 as discussed *supra*.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Demkow et al (Pneumonologia I Alergologia Polska, 1998, provided by Applicant, Examiner is further providing a English language translation) in light of DrugBank (2008, cited to show a fact).

Art Unit: 1614

Demkow et al rifampicin, the elected ansamycin antibiotic inhibits angiogenesis (please refer to pages 10-13 for specific working examples).

DrugBank teaches that rifampicin SV is an alternative name for rifampicin.

*Applicant's Remarks*

Applicant argues that the Demkow et al does not teach the inhibition of angiogenesis in malignant tumors but rather teaches the effects of rifampicin on angiogenesis in mononuclear leukocytes (page 9 of instant response). Applicant cites Yasuda et al which teaches that angiogenesis may be affected by inflammation and as such the mechanism of angiogenesis in malignant tumors differs from that of leukocyte-induced angiogenesis, per Malkowska-Zwierz et al.

*Response to Applicant's Arguments*

Applicant's amendments and remarks have been carefully considered in their entirety, but fail to be persuasive in establishing error in the propriety of the present rejection.

Regarding Applicant's objective of inhibiting angiogenesis (instant claim 1), the rifampicin compound disclosed by Demkow et al. is identical to the compound presently recited (and elected) in Applicant's instant claims.

Therefore, the method of use disclosed by Demkow et al. must necessarily possess the same function in inhibiting angiogenesis as that instantly claimed whether recognized by the Applicant or not because products of identical chemical composition cannot have mutually exclusive properties when used in exactly the same manner. In other words, if the prior art teaches the identical chemical and/or physical structure of the claimed compound and further teaches the identical manner of using the same, the properties that Applicant discloses and/or claims are necessarily present. Please see MPEP §2112.

It is again noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the

Art Unit: 1614

support of rejections wherein the prior art discloses subject matter, which there is reason to believe inherently includes functions that are newly cited, or is identical to a product instantly claimed. In such a situation, the burden is shifted to the Applicants to "prove that subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 594, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention").

### **Conclusion**

No claim is found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNA PAGONAKIS whose telephone number is (571)270-3505. The examiner can normally be reached on Monday thru Thursday, 9am to 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1614

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AP

/Ardin Marschel/  
Supervisory Patent Examiner, Art Unit 1614